Appl. No. 09/964,079
Amdt. dated February 28, 2005
Reply to Office Action of 09/28/2004

PATENT

REMARKS/ARGUMENTS

Claims 1-10 and 26-28 are pending. Claim 6 has been amended to correct a typographical error so as to depend from claim 2, rather than from claim 1. Claims 7-10 and 27-28 have been amended to correct the apparent typographical error with respect to proper antecedent basis for the terms "first level" and "second level." No narrowing amendments are intended.

Independent claim 1 has been amended to incorporate the limitations of dependent claims 2 and 3 which have been cancelled. Dependent claim 4 has been amended to recite that the second level is delivered independent of any feedback from a sensor. Support for all of these amendments can be found through the specification, for example at pages 19. No new matter has been added.

Section 112

Claims 7-10 and 27-28 were rejected under Section 112, second paragraph for lack of antecedent basis. With the amendments to these claims, it is respectfully submitted that this rejection has been overcome.

Section 102

Claims 1-3, 5-9 and 26-28 stand rejected under Section 102(b) as anticipated by Sjostrand et al. Claims 1-10 and 26-28 stand rejected under Section 102(b) as anticipated by Obel and also by Kieval et al. Claims 1, 5, 6 and 26 stand rejected under Section 102(b) as anticipated by Zabara and also by Terry, Jr et al. In light of the amendments to claim 1 and for the reasons set forth, these rejections are respectfully traversed.

In each of the cited references, the stimulation site that is targeted is the vagus nerve or carotid sinus nerve, not the baroreceptors. None of the references teach the positioning of an activation device so as to "preferentially induce a change in the physiologic response of the *baroreceptor*." Unlike the prior art that teaches direct stimulation of the carotid sinus nerve generally located at the apex of the aortic arch, the present invention utilizes targeted stimulation of the baroreceptors in a vascular wall. While the output of an activation device in accordance

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with the present invention will ultimately induce the nervous system, the nerves themselves are not the target of the output of the activation device in the invention as claimed.

Sjostrand teaches stimulation of the carotid sinus nerve during each cardiac cycle. While the reference identifies a need for initial optimization of the mean pulse frequency of a stimulation for a given patient, there is no teaching of automatically controlling the output of a stimulation regimen at two levels as claimed.

Obel teaches stimulation of the carotid sinus nerve in response to comparison of the blood ph and/or oxygen saturation levels with cardiac activity as sensed by various feedback sensors. There is no teaching of automatically controlling the output of an activation device to select a first output level that can more quickly attain the desired physiologic change than a second output level that is better for long term efficacy of the device. The only teaching of automatically making changes to the stimulation of the carotid sinus nerve is in direct response to the various feedback sensors.

Zabara teaches only initial optimization of a stimulation regimen for stimulating the trigeminal and glossopharyngeal nerves (branches of the carotid sinus nerve). There is no teaching or suggestion of automatic controlling the output of that stimulation regimen once it has been optimized.

Terry Jr., et al. teaches stimulation of the vagus nerve based on a prescribed therapy that is optimized at the time of implant. The only alternative described by this reference that adjust the prescribed therapy is in response to sensing of blood pressure or in response to manual intervention by the patient. There is no teaching or suggestion of automatic controlling the output of a stimulation regimen once the prescribed therapy has been established to select a first output level that can more quickly attain the desired physiologic change and then switch to a second output level that is better for long term efficacy of the device.

Finally, Kieval et al. teaches the use of feedback parameters to control stimulation that are obtained from an activity sensor and cardiac activity sensors, and optionally oxygen and

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pressure sensors. Again, there is no teaching or suggestion of automatically controlling the stimulation regimen to select a first output level that can more quickly attain the desired physiologic change and then switch to a second output level that is better for long term efficacy of the device. The only teaching of automatically making changes to the stimulation of the carotid sinus nerve is in direct response to the various feedback sensors.

Section 103

Claims 2-4, 7-10, 27 and 28 stand rejected under Section 103 as being obvious over Terry Jr., et al, in view of Peters et al. This rejection is respectfully traversed for the reasons previously set forth and for the following reasons.

It is admitted in the Office Action that Peters et al. is teaching "carotid sinus nerve stimulation," not stimulation of the baroreceptors. It is also admitted in the Office Action that Peters et al. uses "a proven feedback loop so the stimulation pattern and their patterns can be optimized." (Office Action, page 5). Accordingly, it is respectfully submitted that in light of the amendment to independent claim 1 and the admissions in the Office Action, the combination of Peters et al. with Terry, Jr. et al. would actually teach away from the invention as claimed.

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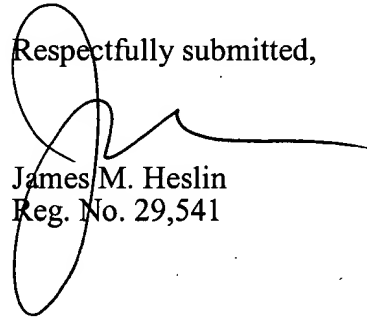Amdt. dated February 28, 2005
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CONCLUSION

In view of the foregoing, Applicants believe all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested.

If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,

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